REMARKS / ARGUMENTS

The action by the Examiner in this application, together with the references cited, has been given careful consideration. Following such consideration, claims 1-5, 7, 9, 10, 12, 16, 18, 21, and 24 have been amended, claim 25 has been added, and claims 6, 8, 11, 13, 17, 19, 20, and 22-23 remain unchanged. This amendment is presented according to "Revised Amendment Practice" (37 C.F.R. 1.121), effective July 30, 2003. It is respectfully requested that the Examiner reconsider the claims in their present form, together with the following comments, and allow the application.

As the Examiner well knows, the present invention relates to a container for holding medical instruments to be microbially deactivated in a reprocessor. More specifically, the present invention relates to a valve disposed in the container.

The container of the present invention includes a tray and a lid. The tray includes a fluid inlet and a fluid outlet. Each inlet and outlet has a flexible valve element disposed therein. The flexible valve element includes a central body portion and an outer, annular, flanged ring portion. The central body portion, or first portion, and the flanged ring portion, or second portion, are connected by a plurality of radially extending arm portions. The flanged ring portion is dimensioned to be fixedly attached to the tray. The valve element is formed of a resilient flexible polymeric material.

The central body portion of the flexible valve element is movable relative to the tray by a mechanical actuator on the reprocessor from a normally closed position to an open position. When the container is inserted into the reprocessor, the central body portion comes into contact with the mechanical actuator on the reprocessor and is moved to an open position. When the

container is removed from the reprocessor, the central body portion is moved to the normally closed position by the action of the resilient arm portions.

The flexible valve element of the present invention is designed such that all surfaces that are exposed to the interior of the container when the central body portion is in the closed position are exposed to a liquid deactivating composition during a deactivation process when the body portion is in an open position. When the central body portion is in the normally closed position, the central body portion engages, or is "seated," against an inner edge of a mounting plate. When the central body portion is in an open position, surfaces of the central body portion, except for the surface contacted by the mechanical actuator, are exposed to the liquid deactivation composition. When the central body portion is in the closed position, the surface that contacts the mechanical actuator is outside of the container and therefore does not pose a risk for recontaminating medical instruments contained within the container.

It is respectfully submitted that none of the cited references teaches, suggests, or shows a container for holding medical instruments as presently set forth in the claims or the advantages thereof.

In response to the Examiner's rejections, the claims have been amended to define more clearly the patentable invention Applicants believe is disclosed herein. Claims 1, 7, and 12 have been amended to indicate that the flexible valve element has "a first portion movable relative to said tray and a second portion fixed relative to said tray."

The Examiner has stated that claim 24 would be allowable if rewritten in independent form including all of the limitations of the base claim and any intervening claims. Claim 24 has been rewritten in independent form to include all of the limitations of claims 1 and 21.

New independent claim 25 has been added and includes all of the limitations of claims 7, 21, and 24. New claim 25 recites, "A container for holding items to be microbially deactivated in a reprocessor, having: a tray for holding said items to be deactivated; a lid operable to cover said tray and to define an interior, sealed cavity that holds said items to be deactivated; a fluid inlet passage into said cavity; a fluid outlet passage into said cavity; at least one valve assembly on said tray associated with each of said passages, said valve assembly including a valve element that is movable through contact with an actuator on said reprocessor between an open position and a closed position, said valve element being movable to said open position when said container is placed within said reprocessor and moving to said closed position when said container is removed from said reprocessor; and a second fluid inlet having a flexible valve element that is movable between an open position and a closed position through contact with a mechanical actuator on a reprocessor, wherein one of said fluid inlets is in fluid communication with a seal defined between said tray and said lid."

The Examiner objected to claims 2, 4-5, 16, and 18 because of informalities. Claims 2, 4-5, 16, and 18 have been amended as required by the Examiner.

Claims 3 and 9-10 stand rejected under 35 U.S.C. 112, second paragraph as being indefinite for failing to point out and distinctly claim the subject matter that the Applicants regard as the invention. The Examiner states that the specification does not provide an explanation for the term "normally." The applicant respectfully submits that one skilled in the art would understand claims 3, and 9-10 based upon how the term "normally" is used in the specification. Namely, in paragraph 59, lines 8 and 9: "All of the valve elements 312 have a *normally closed position* that prevents flow of fluid therethrough."

Claims 1-13 and 16-24 stand rejected under 35 U.S.C. 103(a) as being unpatentable over U.S. Patent No. 5,552,115 to Malchesky in view of U.S. Patent No. 4,445,511 to Bond et al.

The Malchesky reference teaches a decontamination unit for receiving a tray having an attachable lid. The tray has a side wall. Tubing members are connected to a check valve that is connected to an elastomeric grommet, or connector, disposed in the side wall.

As the Examiner states, "the Malchesky reference fails to teach using a flexible valve in the container that is moved by a mechanical actuator in the decontamination chamber."

The Bond et al. reference teaches a quick-disconnect coupling and valve assembly. The valve assembly includes a spout and a valve member disposed therein. The valve member and the spout make contact along a slidable surface. The valve member is axially movable within the spout. A connector member is dimensioned to mechanically engage the valve member. Gripping lugs are provided on the valve member and are dimensioned to mechanically engage a groove that is defined in the connector member. When the connector member and the valve member are mechanically engaged, axial movement of the connector member results in axial movement of the valve member. The valve member is movable in two directions.

Neither the Malchesky reference or the Bond et al. reference teach, suggest, or show a flexible valve element "having a first portion movable relative to said tray and a second portion fixed relative to said tray" as required by claims 1, 7, and 12. Further, neither reference teaches the benefits of such a structure.

The movable structure, i.e., valve, of the Bond et al. reference has surfaces that are partially or wholly covered during the deactivation process, but may be exposed to the medical instruments after the decontamination process. These surfaces are not exposed to the liquid

disinfectant, thus may not be suitably microbially deactivated and may ultimately recontaminate the medical instruments.

To summarize, for medical instruments to remain sterile, all surfaces that are exposed to the medical instruments must also be microbially deactivated. In this regard, valves having sliding structures, e.g., the valve disclosed in the Bond et al. reference, have surfaces that are not exposed to a liquid deactivation composition. Therefore, the valve disclosed in the Bond reference is not suitable and does not ensure that the internal region of the container and the medical instruments therein remain sterile.

The prior art made of record and not relied upon has also been reviewed. It is respectfully submitted that none of these additional references teach or suggest the applicant's invention as defined by the present claims.

In view of the foregoing, it is respectfully submitted that the present application is now in proper condition for allowance. If the Examiner believes there are any further matters which need to be discussed in order to expedite prosecution of the present application, the Examiner is invited to contact the undersigned.

If there are any fees necessitated by the foregoing communication, please charge such fees to our Deposit Account No. 50-0537, referencing our Docket No. ST8725US.

Respectfully submitted,

Date: **November 28, 2005**

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CERTIFICATE OF MAILING UNDER 37 C.F.R. §1.8

I hereby certify that this correspondence (along with any paper referenced as being attached or enclosed) is being deposited on the below date with the United States Postal Service with sufficient postage as first class mail in an envelope addressed to MAIL STOP AMENDMENT, Commissioner for Patents, P.O. Box 1450, Alexandria, VA 22313-1450.

Date: **November 28, 2005**

Laura K. Cahill